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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/807,635 | 03/23/2004 | Daniel E. Afar | S11582001111 | 4032 |
| 25225 | 7590 | 08/21/2006 | EXAMINER | |
| MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040 | | | JOYCE, CATHERINE | |
| | | ART UNIT | PAPER NUMBER | |
| | | | 1642 | |

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/807,635 | AFAR ET AL. |
| | Examiner Catherine M. Joyce | Art Unit 1642 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 May 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 42-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 42-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

1. The Amendment filed May 30, 2006 in response to the Office Action of January 30, 2006 is acknowledged and has been entered. Claims 42-51 are pending and are under examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claims 42-51 remain rejected under 35 USC 112, second paragraph, for the reasons set forth previously in the Paper mailed January 30, 2005, Section 5, page 2.

Applicant argues that the rejection has been addressed by amending the claims to insert the specific wash conditions that correspond to the claim stringency.

Applicant's arguments have been considered but have not been found to be persuasive. Because the stringency of hybridization conditions depends on both the hybridization conditions and the wash conditions, amendment of the claims to include only the wash conditions is not sufficient to overcome the rejection because one of skill in the art would not know the metes and bounds of the invention in the absence of the recitation of both the hybridization and wash conditions.

5. Claims 42, 45, 46, and 49-51 remain rejected under 35 USC 112, first paragraph, for the reasons set forth previously in the Paper mailed January 30, 2006, Section 7, pages 3-5.

Applicant states that a deposit declaration was made in the parent case.

This argument has been considered but has not been found to be persuasive because each case is considered on its own merits, and thus, submission of a deposit

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declaration in each case is required in order to satisfy the requirements of 35 USC 112, first paragraph, and a Deposit Declaration or Affidavit must be filed in this case.

6. Claims 42, 47, and 49-51 remain rejected under 35 USC 112, first paragraph, for the reasons set forth previously in the Paper mailed January 30, 2006, Section 7, pages 3-5. **enablement**

Applicant argues that because the ability to hybridize under stringent conditions is required of the variants, it is evident that these variants would be useful in the detection of 24P4C12 mRNA

Applicant's arguments have been considered but have not been found to be persuasive. Although claim 42 has been amended to include moderately stringent wash conditions, the hybridizing molecules will not be completely complementary and one of skill in the art would not know how to use the variant polynucleotides because, given the moderately stringent conditions now claimed, it would be expected that the hybridizing molecules would hybridize with a whole universe of molecules and would not selectively hybridize to SEQ ID NO:1 to the extent required to predictably distinguish SEQ ID NO:1 from other sequences with a reasonable expectation of success.

7. Claims 42, 43, 47 and 49-51 remain rejected under 35 USC 112, first paragraph, for the reasons set forth previously in the Paper mailed January 30, 2006, Section 7, pages 10-14.

Applicant argues the following: (i) that Lilly is inapposite to the instant case because the claims in Lilly were directed to a specific set of species of cDNA's which were the exact reverse transcripts of mRNA-encoding proinsulin as found in various vertebrate species, wherein for each species there is only one answer which could not be known without retrieving the reverse transcript for that specific mRNA, whereas the instant claims set forth a genus of nucleic acid molecules that are defined structurally by requiring the ability to hybridize to reference substrate or by a percent identity to the protein encoded; and (ii) that Example 14 of the Patent Office Guidelines for written

description approve a claim to a protein having 95% identity to a cited sequence and having the function of catalyzing the reaction of A --> B and that a corresponding functional feature in the instant claims is the ability to immunoreact with antibodies raised against SEQ ID NO:2 (subparagraph a) or to stringently hybridize (subparagraph b).

Applicant's arguments have been considered but have not been found to be persuasive for the following reasons. Applicant argues that Lilly is inapposite to the instant case because the structural features of the members of the genus were not defined in Lilly. This argument is not found persuasive because Lilly is cited for the proposition of stating at least one test wherein the written description requirement might be met by citing a representative number of species of a genus or structural features common to members of the genus. Thus, even though the facts of Lilly can be distinguished from the instant case, it is clear that the claims in the instant case fail to meet the test set out in Lilly because a representative number of species or common structural features were not described in the instant case. For example, a genus comprising all molecules in the genus of claim 42, subparagraph a, would, by definition, not share a common structural feature because whatever structural feature is contemplated, that feature will vary in at least some members of the genus. Applicant argues that the Patent Office Guidelines for written description specifically approve the types of claims presented here because Example 14 of the Guidelines approves a claim to a protein having 95% identity to a cited sequence and having the function of catalyzing the reaction of A --> B. Applicant argues limitations not found in the claims. Example 14 cites a claim that, unlike the instantly claimed invention, clearly identifies the function of the molecule and relates that function to a specific structure, and thus does not support the proposition that the instant claims are supported by a written description.

FINALLY, it is noted that neither the structure on the claimed variant to which the antibody that reacts to SEQ ID NO:2 binds, nor the sequences to which the hybridizing

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molecule hybridizes under the moderately stringent conditions claimed, are defined by the specification and thus, the specification provides no nexus between structure and function as required to satisfy the requirements of 35 USC 112, first paragraph.

Thus, the rejection of claims 42-47 and 49-51 as failing to comply with the written description requirement is maintained.

New Grounds of Rejection

8. Claims 42-51 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention.

The limitation of "correcting to wash" recited in claim 42 has no clear support in the specification and the claims as originally filed. A review of the specification discloses a description of stringency hybridization and wash conditions on page 12, lines 1-13. However, a description of the concept "correcting to wash" is not found.
The subject matter recited in claim 42 broadens the scope of the invention as originally disclosed in the specification.

9. No claims are allowed.

10. Claims 44, 48 would be allowable if written in independent form.

11. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY

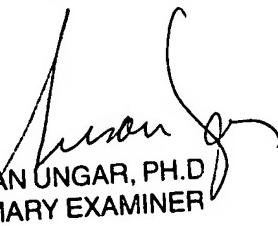
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PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Catherine M. Joyce
Examiner
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